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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CHAPMAN, GINGER T

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/784,336	Applicant(s) JORGENSEN ET AL.	
	Examiner Ginger T. Chapman	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,5 and 8-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,5 and 8-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 12/26/2007 have been fully considered but they are not persuasive.
2. Applicant argues the following:
3. A. With respect to independent claim 4, Applied references lack a needle set comprising a hollow needle coupled with a tube having a fitting (remarks, p. 8).
4. This argument is not persuasive because McEwan teaches a needle inserted into a cap assembly. The point of insertion into the cap assembly is the point at which the needle is fitted into the cap assembly performs the same function as a fitting and thus can be considered to comprise a fitting. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the claimed assembly comprising since it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art. *In re Karlson*, 136 USPQ 184.
5. B. The applied references lack a first port in an elongated container because the port of Kelly (116) functions differently than the instant claimed port because the instant port may be opened and closed as needed. (Remarks, p. 9).
6. This argument is not persuasive because Kelly teaches at column 9, lines 2-4 that the port of Kelly is comprised of a self-sealing type plug that swells when contacted by the blood to close the opening, thus the port of Kelly is considered to close when needed, i.e. when contacted by blood.

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7. C. The applied references lack the acts of moving the plunger toward the first port and expelling the red blood cells into a waste bag through tubing attached to the port (remarks, p. 9).

8. This argument is not persuasive because the Coleman teaches moving the plunger toward the first port and expelling the red blood cells into decanters (c. 6, ll. 63-69). McEwan teaches the separated sebum is removed or withdrawn after separating and is decanted into a waste container. Thus the prior art contains all that is claimed except for being provided in two references instead of contained in one reference.

9. D. The applied references lack a second centrifuging act (Remarks, p. 10).

10. This argument is not persuasive because multiples of the same step do not add additional patentable weight and is an obvious modification. In addition, it has been held that where the general conditions of a claim are disclosed in the prior art (here, centrifuging), discovering the optimum or workable ranges (here, duration or frequency of centrifuging), involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

11. E. The applied references lack the act of attaching the plunger having a third port and displacing the plasma into a waste bag (remarks, p. 11).

12. This argument is not persuasive for the reasons detailed *supra* under C.

13. With respect to independent claims 5 and 16, Applicant argues claims 5 and 16 include many of the same claim elements as independent claim 4 and thus are allowable for the same reasons (remarks, pp. 13 and 14).

14. This argument is not persuasive for the reasons detailed *supra*.

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Status of the claims:

Claims 4, 5 and 8-18 are pending in the application.

Withdrawn Objections:

The objection to claim 4 made of record in the previous Office action is withdrawn in view of the corrected status identifier as (Currently Amended).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims 4, 5, 8-10, 12-13 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over McEwen et al. (4,828,716) in view of Coleman (US 3,508,653) in view of Kelly et al. (6,074,883) and further in view of Furse (US 5,354,483).

With regard to **claims 4-5 and 16**, McEwen discloses a method wherein blood is collected from a patient using a needle set and collected or transferred into a container and tubing is connected to the container for delivery and withdrawal of components. The container has a piston (closure 16) that moves as a result of the centrifugation to separate the blood into its components. The container is placed within a centrifuge for a spin to separate the blood into its components. McEwen teaches that the separated serum is removed or withdrawn after separating and is decanted (i.e. is expelled into a waste container). See figures 1a-1g; col. 7, line 28 to col. 9, line 49. McEwen also teaches that the components may be further separated by centrifugation until desired separation of components is achieved. Col. 14, lines 43-51.

McEwen et al disclose the method substantially as claimed except for disclosing specifically the following: the step of attaching a hollow plunger rod with a port to displace separated platelet-poor plasma by moving the plunger toward the first port; a "soft" and "heavy" spin; that the separated red blood cells are expelled is into a waste bag; or that the collection container contains a small amount of anti-coagulant.

Coleman discloses a method of collecting and separating a patient's blood. At c. 6, ll. 63-69, Coleman teaches the plunger and rod comprising second and third ports, thus disclosing a desire for such. Coleman teaches that the plunger can comprise a hollow rod having a second and third port, i.e. the ports on either end of the axial passageway comprising the plunger, and teaches displacing the separated platelet poor plasma by moving expelling the plasma through the second and third ports of the plunger rod thereby separating and decanting the blood products (c. 6, ll. 63-69). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the plunger rod of McEwan having a third port

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therein as taught by Coleman since Coleman states at c. 6, ll. 63-69 that the benefit of practicing the method with this step is that it permits the passage of the light phase, i.e. the plasma, upwards through the plunger rod such that it can be removed from the chamber.

With respect to the limitation of **claims 4 and 16: step (b)**, transferring the blood from the needle through the tubing, fitting and first port into the container by moving the plunger away from the first port, Coleman teaches at c. 5, ll. 60-66 that if the tube or chamber has been previously evacuated then blood will flow from the individual through a needle into the collection tube as the vacuum draws blood through the ports and into the tubing. Additionally, it is known in the blood withdrawal art that moving the plunger within a syringe chamber causes the blood to flow toward the plunger by means of the reduction in pressure created by moving the plunger, again as the vacuum created draws blood through the ports and into the tubing. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made that the step of transferring the withdrawn blood from the patient into the blood separation chamber necessarily and inevitably results in the blood being transferred through tubing and a port since all of the components are fluidly connected in serial.

With respect to the limitation of **claim 5, steps b, c and d**, McEwan in view of Coleman disclose the claimed invention but do not expressly disclose opening valves positioned within ports. Furse, at c. 1, ll. 17-20, expresses the desire to provide means for separating a patient's blood wherein the chamber has ends separated by a displacing plunger such that a first end of chambers can receive the blood and a pre-selected phase of the blood may be received from the other end. As seen in Figures 1 and 3a, Furse teaches opening a valve (14) positioned within first port (54) whereby blood is transferred into first port (14) by moving plunger (18) away from

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the first port and closing the valve (c. 9, ll. 14-17; c. 8, ll. 47-55). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the methods of McEwan/Coleman to include the step of transferring the blood into the container as taught by Furse since Furse states at c. 9, ll. 10-15 that the benefit of performing the method in this manner is that blood can be introduced into the container and thereafter separated into phases.

With respect to **claims 8 and 9**, McEwen teaches that the centrifuge has a motor and control device that can control the speed as desired. Therefore, a "soft" and "heavy" spin may be achieved by the method of McEwen. Since McEwen teaches that separated serum is removed or withdrawn after separating and is decanted (i.e. is expelled into a waste container) it would be an obvious step in such a method to choose to decant separated red blood cells into a bag to one having ordinary skill in the art. If red blood cells are not the desired end product of the method, there would be no reason to keep them and decanting or expelling them into a waste container is standard operating procedure in medical laboratories. With respect to using a waste bag, a container is an equivalent to a bag.

With respect to **claims 10 and 13**, it would have been obvious to perform the displacing step manually or automatically since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art, *In re Venner*, 120 USPQ 192.

Applicant has provided no criticality for the step to be performed manually or automatically, the specification contains no disclosure of either the critical nature of the claim limitations nor any unexpected results arising therefrom, and that as such the limitations were

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arbitrary and therefore obvious. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with performing the step either manually or automatically because both perform the same function of displacing the cells and plasma, and in the instant case substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency, *In re Fount* 213 USPQ 532 (CCPA 1982); *In re Siebentritt* 152 USPQ.

With respect to **claims 12 and 15**, it would have been obvious step to one having ordinary skill in the art to include an anti-coagulant in the container since it is standard operating procedure in blood collection.

With regard to claims **17 and 18**, reciting the limitations of the ports including valves, the method comprising the steps of opening the valves, opening and closing valves are known from everyday use and therefore the step of opening valves would be obvious to one of ordinary skill in the art at the time the invention was made, for detailed discussion of opening the valves, see also claim 5, steps b, c and d, detailed *supra*.

Allowable claims

Claim 11 is allowed.

The following is an examiner's statement of reasons for allowance: The subject matter not found was the step of displacing red blood cells, platelet-rich plasma, and platelet-poor plasma automatically in a centrifuge that facilitates opening the ports in combination with the other steps (or elements) in the claim reciting displacing the cells from the container by moving the plunger and expelling the cells through the tubing attached to the port.

Allowable Subject Matter

Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The subject matter not found was the step of displacing red blood cells, platelet-rich plasma, and platelet-poor plasma automatically in a centrifuge that facilitates opening the ports in combination with the other steps (or elements) in the claim reciting displacing the cells from the container by moving the plunger and expelling the cells through the tubing attached to the port.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/
Examiner, Art Unit 3761
4/27/08
/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772